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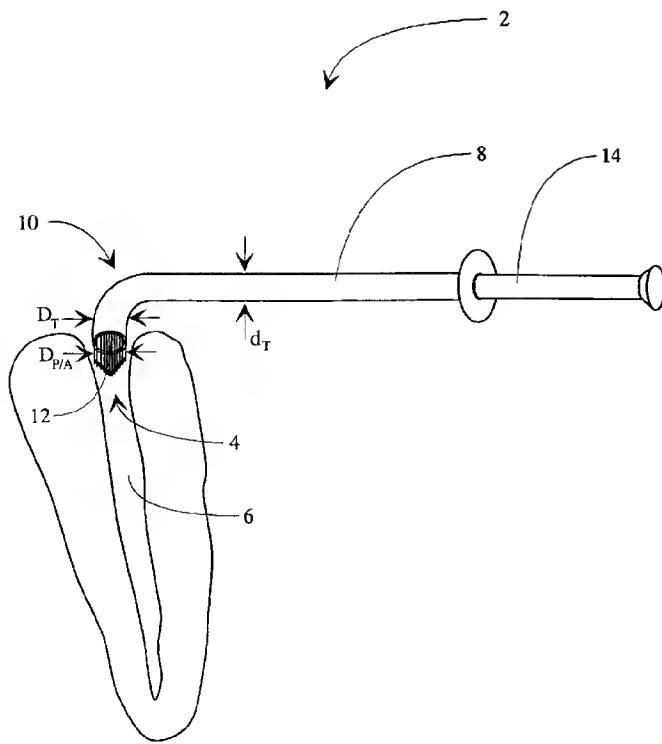
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(54) Title: APPLICATOR SYSTEM FOR DENTAL POSTS AND ANCHORS AND USE OF SAID APPLICATOR SYSTEM



WO 03/005927 A1



(57) **Abstract:** The invention relates to an applicator system (1) for application of a prefabricated reinforced composite post or anchor in its non-cured form into a dentinal canal (3). The invention is characterized in that the applicator system (1) comprises a prefabricated fiber-reinforced composite post or anchor in its non-cured form comprising a matrix and fibers, and an applicator tube (5) having a first end and a second end, wherein the inner diameter d_T of said tube (5) is at most 5 % larger than the outer diameter $D_{P/A}$ of said post or anchor in its non-cured form, and the outer diameter D_T of the second end of said tube (5) through which the post or anchor is applied into the dentinal canal (3) is 0,5-2 mm. The invention further relates to the use of said applicator system.



TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

APPLICATOR SYSTEM FOR DENTAL POSTS AND ANCHORS AND USE OF SAID APPLICATOR SYSTEM

FIELD OF INVENTION

5 This invention relates to an applicator system for application of a prefabricated reinforced composite post or anchor in its non-cured form into a dentinal canal. This invention further relates to the use of the system.

BACKGROUND OF THE INVENTION

10 The publications and other materials used herein to illuminate the background of the invention, and in particular, cases to provide additional details respecting the practice, are incorporated by reference.

Existing systems for anchorage of dental constructions such as crowns and large fillings to remaining roots are based on the use of dental posts mostly made of high rigidity materials like metal alloys, ceramics or to reduce the rigidity they can be 15 made of completely polymerized fiber reinforced composite materials as disclosed e.g. in US 5,964,592. Common characteristics of these posts are that when they are delivered and thus when they are inserted, they are in their final straight shape and that they are rigid. Occasionally they exhibit tapered or structured surfaces for increased mechanical retention for the composite luting cements. The earliest fiber 20 reinforced composite (FRC) posts were made of carbon/graphite fibers with epoxy polymer matrix resulting in flexural modulus of 40 to 60 GPa. The most recent FRC posts are made of glass or silica fibers with an epoxy or dimethacrylate polymer matrix having flexural modulus between 28 to 40 GPa. Clinically the advantage of FRC posts has been that these do not cause fracturing of roots even if they have 25 been used in short post lengths compared to the length of the clinical crown. On the

other hand, the fracture incidence with metallic and ceramic posts has been high. The biggest disadvantages of completely polymerized FRC posts are the low bonding strength between the FRC post and the composite luting cement or composite core material, and the inability to bend along the curved root canal. All 5 commercially available FRC posts require preparing the root canal to the standardized form of the FRC post. The preparation reduces the quantity of dentine and thus, reduces strength of the remaining root. These shortcomings cause frequent debonding of the FRC posts from the core and cement and hamper seriously the preparation of curved root canals. As a result of the present preparation techniques 10 perforation of the tooth root and the periodontal ligament often occurs resulting in an elevated risk of infection of periodontal tissues. On the other hand, if there is need for long post lengths, which is the case when using metallic or ceramic posts to reduce the functional stress at the end point of the post, the root canal sealing has been shown to deteriorate considerably. This can cause an infection, e.g. a periapical 15 periodontitis. Therefore a post system with an improved bonding characteristic that can be placed in curved individually shaped root canals even with short post lengths would be a welcome improvement.

It is known that polyethylene fiber products are being marketed for making posts *in situ*. The polyethylene fibers are inserted into the root with a special handheld 20 instrument by pushing the fiber ribbon from the middle. The root canal is filled with a dual curing composite to wet the fibers and to bond the post to the tooth root surface. The potential advantages of this system are that there is no interface between the post polymer matrix surface and the cement since it is of the same material and that there is no need to prepare straight cavities for the posts.

25 Disadvantages of a polyethylene fiber post system are that wetting of the fibers by the polymer matrix and bonding of the fibers to the polymer matrix are inadequate (Vallittu, Ultra-high-modulus polyethylene ribbon as reinforcement for denture polymethyl methacrylate. Dent Mater 1997;13:381-382), the control of wetting the

fibers inside the root is impossible and use of woven fibers results in less than optimal orientation of the fibers in the root.

The state of the art fiber reinforcement material in dentistry is preimpregnated unidirectional glass fiber material as disclosed e.g. by Sicurelli & Masyr 5 (WO 98/52486). There are four such materials available commercially: Jeneric Pentron's Fibrekor®, Ivoclar-Vivadent's Vectris®, Stick Tech's Stick® and everStick™. These differ from the other fiber materials in two respects: the bonding between the fiber surface and the polymer matrix is significantly higher than with polyethylene fibers and the wetting of the fibers with the polymer matrix is 10 complete. This results in flexural strengths of up to 1280 MPa as compared to 350 MPa of the best polyethylene product and in elastic modulus of up to 28 GPa as opposed to 3–5 GPa of polyethylene composites.

The disadvantage of unidirectional glass fibers is their poor controllability in the clinical handling process. Considering a root canal of dimensions approximately 15 2 mm opening diameter and 1 mm end diameter, 5–10 mm length and being of considerable curvature imposes various problems for the insertion of a unidirectional, non woven, non twisted glass fiber bundle of approximately 1 000 to 6 000 individual fibers, impregnated with a low viscosity monomer liquid. The fibers fray, bend and tangle with each other when one tries to push them inside the 20 canal. Once spread, it is next to impossible to collect the fibers back into order and try again.

Very similar devices to posts are root canal anchors called root canal screws that are actually just very short posts. These are manufactured in the form of a metallic screw of maximum length of approximately 10 mm and minimum length of 3 mm. 25 In fact the division between an anchor and a post is not clear. In both cases however the root canal is prepared with a separate straight drill to make a close fit cavity for the screw. On the other hand, the screws can also be placed into other dentinal cavities and canals, such as those prepared in a vital tooth. These vital tooth screws

are called parapulpal posts and they are most often used to improve retention of fillings to remaining teeth.

The indication for an anchor is the need for added fixation of a partial crown or filling of large dimensions. Fillings are generally attached through mechanical or 5 chemical retention or both. The strength of chemical retention depends on bonding surface area and roughness and the chemical nature of the bond. Mechanical retention depends solely on the shape and surface roughness of the cavity. One could say that the less of the tooth is left for mechanical or chemical bonding the more important it is to create increased retention of posts and anchors. In this sense 10 a crown with very little tooth support left is an extreme case of a filling and is a clear indication for a root canal post. The other extreme is a one-wall filling that in practice usually does not need any additional retention from a post nor an anchor. With larger cavities involving 2 or 3 walls, larger than that being already considered 15 crowns, the achievable retention is dramatically reduced and there is an increasing need to create more retention artificially.

OBJECT AND SUMMARY OF THE INVENTION

The object of the present invention is to provide an alternative and/or improved system for application of a reinforced composite post or anchor into a dentinal canal. The object of the present invention is specifically to provide a system for 20 application of a post or anchor that does not have the above-mentioned drawbacks and that allows the positioning of a post or anchor without the fibers fraying, bending and tangling with each other.

The invention is defined in the appended claims.

The present invention concerns an applicator system for application of a 25 prefabricated reinforced composite post or anchor in its non-cured form into a dentinal canal. The invention is characterized in that the applicator system comprises a prefabricated fiber-reinforced composite post or anchor in its non-cured

form comprising a matrix and fibers and an applicator tube having a first end and a second end, wherein the inner diameter d_T of said tube is at most 5 % larger than the outer diameter $D_{P/A}$ of said post or anchor in its non-cured form, and the outer diameter D_T of the second end of said tube through which the post or anchor is applied into the dentinal canal is 0,5-2 mm.

5 The present invention further concerns the use of the applicator system for preparing permanent or temporary root canal posts for fixation of artificial crowns and/or for the treatment of endodontic and/or periapical infections, for making a root canal filling and for making a post and/or anchorage system that forms a continuous 10 structure from the apex of the tooth to the coronal part of the tooth.

BRIEF DESCRIPTION OF THE DRAWING

Figure 1 shows the use of an applicator system according to the invention when applying a root canal post into the root canal.

DETAILED DESCRIPTION OF THE INVENTION

15 The present invention provides an applicator system for application of a prefabricated reinforced composite post or anchor in its non-cured form into a dentinal canal. The invention is characterized in that the applicator system comprises a prefabricated fiber-reinforced composite post or anchor in its non-cured form comprising a matrix and fibers and an applicator tube having a first end and a second end, wherein the inner diameter d_T of said tube is at most 5 % larger than the outer diameter $D_{P/A}$ of said post or anchor in its non-cured form, and the outer diameter D_T of the second end of said tube through which the post or anchor is applied into the dentinal canal is 0,5-2 mm. The inner diameter d_T of said tube may 20 be for example 4,5 %, 4 %, 3,75 %, 2,4 %, 2 %, 1,5 %, 0,9 % or 0,2 % larger than the outer diameter $D_{P/A}$ of said post or anchor. 25

In this context the dentinal canal refers to a root canal of a tooth or any canal of the tooth e.g. prepared for improving retention of fillings to remaining teeth by anchorage. By curing it is meant both polymerizing and cross-linking. The words "impregnating" and "wetting" may also be used interchangeably, i.e. a single fiber is 5 wetted and a fiber bundle is either wetted or impregnated, both terms meaning that the material used for said wetting or impregnation is well distributed between the fibers and within the fiber bundle.

The present invention thus proposes an applicator system allowing the positioning of a post or anchor without difficulty. The use of an applicator according to the 10 present invention ensures that the fibers of a finished post or anchor are in the same position with respect of each other than in the prefabricated post or anchor.

The outer diameter of the second end of the tube through which the post or anchor is applied into the dentinal canal is chosen between 0,5-2 mm, so that its outer diameter is preferably essentially identical to the coronal opening of the root canal 15 or other cavity in which the post of anchor is to be applied, or it is smaller than said opening or cavity.

The applicator system thus comprises a prefabricated fiber reinforced composite (FRC) post or anchor, also called a prepeg, i.e. a FRC post or anchor in its non-cured form, and a tube by which said prepeg can be pushed into a tooth canal. The 20 prepeg comprises a matrix and fibers. The matrix may be composed of a monomer, a cross-linkable polymer or a mixture of a polymer and a monomer and optionally filler materials such as ceramic powder and/or opaquers, plasticizers etc. The matrix may also comprise one or several polymerization initiators. The material of the matrix may be any suitable material for dental applications, known to a person skilled in the art, such a poly(methyl methacrylate).

The fibers are preferably essentially continuous and/or essentially unidirectional. Fibers are most preferably used as a fiber bundle wherein the fibers are not twisted.

The fibers are preferably glass fibers, silica fibers, carbon/graphite fibers, aramid fibers, Spectra®-fibers, Mylar®-fibers, polyethene fibers, polypropene fibers or other polyolefin fibers, quartz fibers, ceramic fibers such as aluminium oxide fibers, silica carbide fibers (SiC-fibers) or SiAlON-fibers.

5 The applicator tube may be stiff or flexible, transparent, opaque or partially opaque. The essential requirement is that the inner diameter d_T of the tube is only slightly larger than the outer diameter $D_{P/A}$ of the FRC post or anchor, i.e. the diameter occupied by the volume of the fibers. Said inner diameter d_T may be identical to said outer diameter or it may be at most 5 % larger than said outer diameter. If in
10 such confinement a force is applied to one end of the fibers the entire length of the fiber bundle moves inside the tube without being able to fray, bend or tangle. The end of the tube is placed directly on or marginally inside a root canal opening or the opening of a dentinal canal prepared to a vital tooth. The outer diameter D_T of the tube is essentially the same or slightly smaller than the coronal opening of the canal,
15 at most 5 % smaller than said opening. Thus the canal forms a continuation of the tube thereby enabling trouble free transfer of the fibers into the canal. If nevertheless something goes wrong and the fibers are frayed, bent or tangled they can be pulled back into the tube which forces the fibers in perfect order again.

20 The matrix of the post or anchor can be cured by light initiation and/or by autocuring in the dentinal canal. If the applicator tube is transparent and flexible it is easy to check the wetting of the fibers. If the fibers are prewetted the tube may also be opaque. In the latter case wetting can only be done using a light curing resin. The fibers of the post or anchor can comprise optical fibers allowing light curing of the matrix in the dentinal canal. It is thus possible to use the present applicator either
25 such that the prefabricated post comprising both matrix and fibers is delivered within the applicator tube or that only the fibers are present in the applicator tube and the matrix is added shortly prior to the positioning of the post or anchor.

Once the fibers are in place in the canal the outside portion of the fibers, i.e. the coronal part may be placed in any direction wished. This allows the dentist to direct the core part of the post or anchor in an optimal direction for building of the crown or filling. If the fibers are unidirectional this may be done without compromising the 5 strength of the construction. Since the matrix of the post or anchor prepreg is cured in the root canal, with or without additional composite luting cement, the additional cements or dentine adhesives are chemically adhered to the FRC post or anchor during curing. After being cured in the root canal and twisted to the desired direction according to the angulation of the crown or filling to be made, the core 10 particulate filler composite material is cured to the oxygen inhibition layer of the coronal part of the post or anchor. This results in a durable bond between the core composite and post or anchor. The fibers may be wetted at the factory with a light curing resin (prepreg) or at the dentist office using a dual curing resin. This is to say that in the embodiments according to the invention described above the fibers may 15 or may not be prewetted with a matrix when sold.

For molar regions it may be preferential that the tube is temporarily or permanently shaped into an arch so as to be able to bring the tube to the canal opening from an optimal direction.

The end of the fiber bundle may be cut into a conical shape so that the tip of the 20 bundle is pointed or blunt but only a fraction of the main fiber bundle is cut in such a way. Indeed, it is possible that an important part of the length of the post is truncated but not all of its length. This is to allow the shape of the fiber bundle to better fit to the shape of the root canal.

The insertion force may be applied to the end of the fibers by a separate piston well 25 fitted to the diameter of the applicator tube. Another way is to precure the rear end of the fiber bundle, through which the insertion force is applied, into the shape of a piston. Typically about 1 to 2 mm of the rear end of a post of 5-10 mm is cured. Thus the fibers partially outside and partially inside the tube would be stiff whilst

the other end of the fibers would be non-cured, elastic and maybe even non-impregnated with resin. However they may be preimpregnated with a polymer or a polymer-monomer gel according to earlier inventions disclosed by Vallitu et al. (WO 96/25911 and WO 99/45890) or with a monomer or any mixture containing monomer or polymer. Such mixtures could contain e.g. microfillers, opaques or alike.

The tip of the prefabricated post could be cured into a shape that easily penetrates into the root canal and finally stops at the apex. The polymerized apical tip can additionally contain antimicrobial agents to heal the apical periodontal infections.

10 The post or anchor can be used as a temporary or permanent root canal filling material.

The invention further relates to the use of an applicator system according to the invention for the production of a tooth canal filling. The invention also relates to the use of an applicator system according to the invention for preparing permanent or temporary root canal posts for fixation of artificial crowns, for the treatment of endodontic and/or periapical infections as well as for making a post and/or anchorage system that forms a continuous structure from the apex of the tooth to the coronal part of the tooth.

DETAILED DESCRIPTION OF THE DRAWING

20 Figure 1 shows the use of an applicator system 1 according to the invention when applying a root canal post 2 into the root canal 3 of a tooth 4. The applicator system 1 comprises an applicator tube 5 having a first end 6 and a second end 7 through which the post 2 is applied into the dentinal canal 3. The Figure illustrates the dimensions mentioned, the inner diameter d_T of the applicator tube 5, the outer diameter $D_{P/A}$ of the post 2 and the outer diameter D_T of the second end 7 of the tube 5.

The Figure further shows a separate piston 8 of the applicator system by which the post 2 is pushed through the second end 7 of the applicator tube 5. The end of the fiber bundle forming the post together with the matrix is cut into a conical shape so that it fits better to the shape of the bottom of the root canal 3. The applicator tube 5 is shaped into an arch so as to be able to bring the tube 5 to the canal opening from an optimal direction.

In this specification, except where the context requires otherwise, the words "comprise", "comprises" and "comprising" means "include", "includes" and "including", respectively. That is, when the invention is described or defined as comprising specified features, various embodiments of the same invention may also include additional features. Also, the reference signs should not be construed as 10 limiting the claims.

CLAIMS

1. An applicator system for application of a prefabricated reinforced composite post or anchor in its non-cured form into a dentinal canal, **characterized** in that the applicator system (1) comprises
 - a) a prefabricated fiber-reinforced composite post or anchor in its non-cured form comprising a matrix and fibers, and
 - b) an applicator tube (5) having a first end and a second end, wherein
 - i) the inner diameter d_T of said tube (5) is at most 5 % larger than the outer diameter $D_{P/A}$ of said post or anchor in its non-cured form, and
 - ii) the outer diameter D_T of the second end of said tube (5) through which the post or anchor is applied into the dentinal canal (3) is 0,5-2 mm.
2. The applicator system according to claim 1, **characterized** in that said fibers of said post or anchor are essentially continuous and essentially unidirectional.
3. The applicator system according to claim 1 or 2, **characterized** in that said fibers are glass, silica, carbon, graphite, aramid, polyethene, polypropene, quartz, aluminium oxide, silica carbide or SiAlON fibers.
4. The applicator system according to claim 1, 2 or 3, **characterized** in that said applicator tube (5) is flexible or rigid.
5. The applicator system according to any of claims 1 to 4, **characterized** in that said applicator tube (5) is transparent or opaque.
6. The applicator system according to any of claims 1 to 5, **characterized** in that said matrix of the post or anchor is light curable or autocurable.

7. The applicator system according to any of claims 1 to 6, **characterized** in that the post or anchor comprises optical fibers.

8. The applicator system according to any of claims 1 to 7, **characterized** in that the end of the post or anchor first applied into the root canal (3) is precured and/or wetted with antimicrobial agents.

9. The applicator system according to any of claims 1 to 8, **characterized** in that said prefabricated composite post or anchor is positioned inside said applicator tube (5).

10. The applicator system according to any of claims 1 to 8, **characterized** in that only the fibers of said prefabricated composite post or anchor are positioned inside said applicator tube (5).

11. Use of an applicator system according to any of claims 1 to 9 for the production of a tooth canal filling.

12. Use of an applicator system according to any of claims 1 to 9 for preparing permanent or temporary root canal posts for fixation of artificial crowns and/or for the treatment of endodontic and/or periapical infections.

13. Use of an applicator system according to any of claims 1 to 9 for making a post and/or anchorage system that forms a continuous structure from the apex of the tooth to the coronal part of the tooth.

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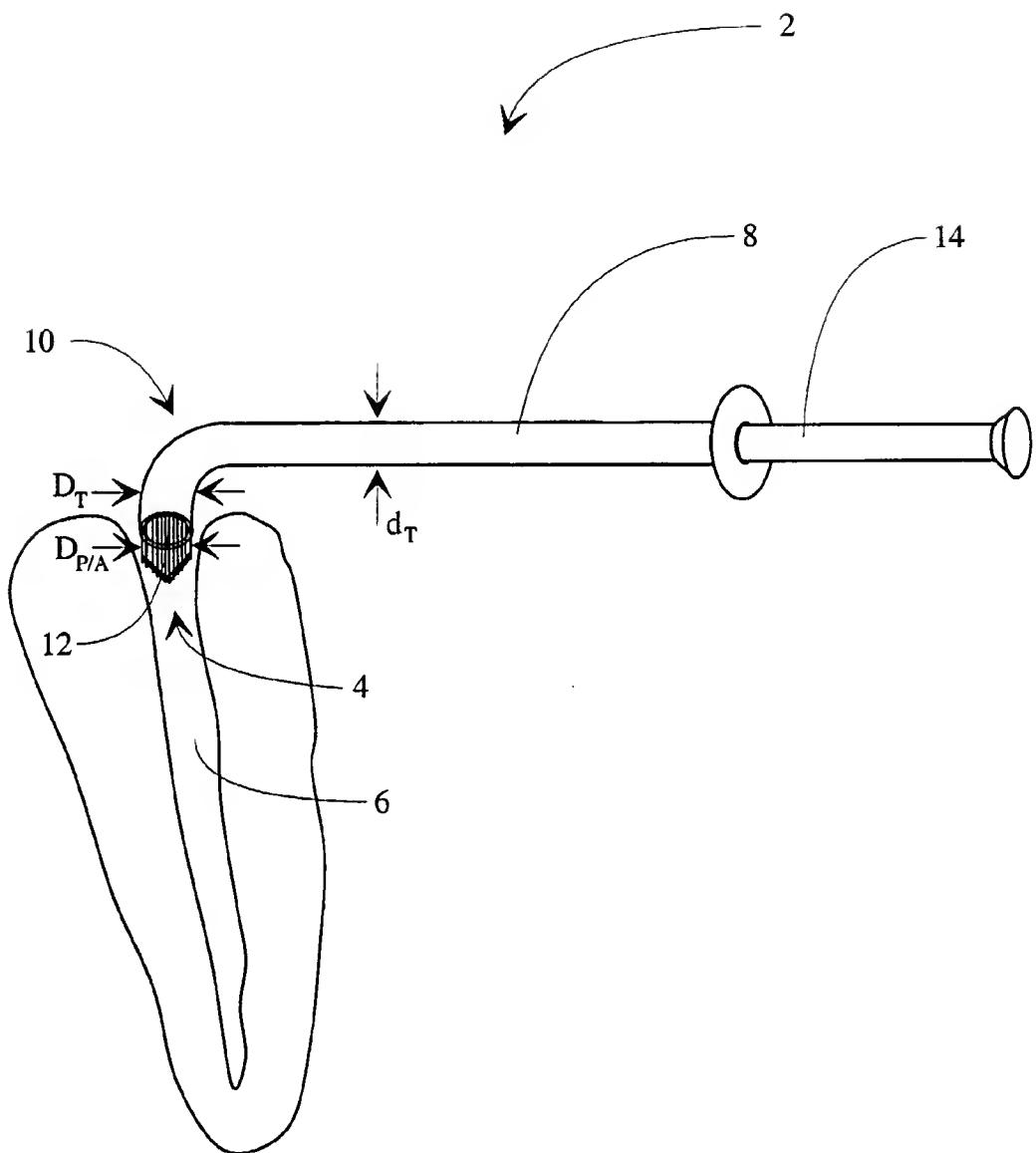


Fig. 1

INTERNATIONAL SEARCH REPORT

International application No.

PCT/FI 02/00625

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61C 5/04, A61C 5/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61C, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5445523 A (DAN E. FISCHER ET AL), 29 August 1995 (29.08.95), figures 1-5, claims 1-16 --	1-10
A	US 4472141 A (WILLIAM B. DRAGAN), 18 Sept 1984 (18.09.84), figures 1-17, claims 1-45 --	1-10
A	US 5919044 A (ROBERT J. SICURELLI, JR. ET AL), 6 July 1999 (06.07.99), figures 1-17, claims 1-30 -- -----	1-10

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

- "&" document member of the same patent family

Date of the actual completion of the international search

24 October 2002

Date of mailing of the international search report

28-10-2002

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INTERNATIONAL SEARCH REPORTInternational application No.
PCT/FI 02/00625**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: **11-13**
because they relate to subject matter not required to be searched by this Authority, namely:
Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods. See PCT Rule 39.1(iv)
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

30/09/02

International application No.

PCT/FI 02/00625

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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